



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/289,000	02/25/1997	GERALD BLATT	16683-1-2	8112

7590

03/21/2002

TOWNSEND AND TOWNSEND AND CREW
TWO EMBARCADERO CENTER, 8TH FLOOR
SAN FRANCISCO,, CA 94105

EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 03/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/289,000

Applicant(s)

BLATT, GERALD

Examiner

Paul B. Prebilic

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-10 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-10 and 24-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 May 1995 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 3738

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 27, 2001 has been entered.

Drawings

Figure s 1B to 1E should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 3738

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-6, 8-10, and 24-31 are rejected under 35 U.S.C. 102(b) as anticipated by Cohen (US 5,207,712) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cohen (US 5,207,712) alone. Cohen (US 5,207,712) anticipates the claim language wherein the resection of bone ends or the holes drilled into the bone ends expose the cancellous bone surface and the solid sphere and rods allow both for the joint to flex and extend after implantation (see Col. 4, lines 38 and 39) and the ball (4) provides a sliding surface for the joint ends; see the whole document, especially Col. 3, lines 18-20; Col. 4, lines 3-39 and Figures 1-3 and 8-11.

Alternatively, one could view the ball (4) as not providing a sliding surface because it is not explicitly stated as providing such. However, the Examiner posits that one viewing this embodiment would be led to the conclusion that the ball (4) obviously functions as a stop and sliding surface for the resected bone ends because the joint flexes and extends around the ball surface; see column 4, lines 38-39.

With regard to claims 8 and 9, Applicant is directed to Figure 1 and especially Figure 2 for claim 8. It is noted that the first and second face of Cohen is on opposed sides of the spacer such that it reads on the claim language.

With regard to claim 24 specifically, the Examiner posits that a period of 6 to 7 months would be sufficient to allow all the natural processes of the permitting step as claimed to take place; see Col. 2, lines 45-48.

Art Unit: 3738

With regard to claims 4, 10, and 25 specifically, the estimating step as claimed is inherently or implicitly present in Cohen who makes his device for a particular joint type so that as much regrowth between the joints can take place.

Claims 2 and 3 are rejected under 35 U.S.C. 103 as being unpatentable over Cohen (US 5,207,712) in view of Delcommune et al (US 5,007,939). Cohen meets the claim language except for the use of lactic acid polymer or copolymer as claimed. Delcommune et al, however, teaches that it has been known to use lactic acid polymer or copolymer for resorbable bone repair devices. Hence, it is the Examiner's position that it would have been obvious to one of ordinary skill in the art to use lactic acid polymer or copolymer in place of in addition to the polymer of Cohen for the same reasons that Delcommune et al uses the same and in order to further reduce the cost of making the device.

Response to Arguments

Applicant's arguments filed November 27, 2001 have been fully considered but they are not persuasive.

The declaration under 37 CFR 1.132 filed November 27, 2001 by Gerald Blatt is insufficient to overcome the rejection of claims 1-6, 8-10, and 24-31 based upon Cohen as set forth in the last Office action because:

In response to the traversal that sliding motion would not be possible with the Cohen device and bone joint fusion would result, the Examiner posits that this argument directly contradicts Cohen which states that knitting of the bone ends is prevented by the gap provided; see the abstract and column 4, lines 37-39. In addition, fibrous growth

Art Unit: 3738

is only present after some time post-implantation so sliding motion is at least still present initially.

The Blatt declaration provides no objective evidence of unobviousness. Rather, arguments are provided to explain why Blatt, the present inventor, believes that Cohen would result in a fused joint. For this reason, the probative value of such a declaration is less than that of a declaration providing objective evidence.

The following is an excerpt from MPEP 716.01(c):

"To be of probative value, any objective evidence should be supported by actual proof. Objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See, for example, *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("It is well settled that unexpected results must be established by factual evidence." "[A]ppellants have not presented any experimental data showing that prior heat-shrinkable articles split. Due to the absence of tests comparing appellant's heat shrinkable articles with those of the closest prior art, we conclude that appellant's assertions of unexpected results constitute mere argument."). See also *In re Lindner*, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972); *Ex parte George*, 21 USPQ2d 1058 (Bd. Pat. App. & Inter. 1991)."

"In assessing the probative value of an expert opinion, the examiner must consider the nature of the matter sought to be established, the strength of any opposing evidence, the interest of the expert in the outcome of the case, and the presence or absence of factual support for the expert's opinion. *Ashland Oil, Inc. v. Delta*

Art Unit: 3738

Resins & Refractories, Inc., 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985)." (emphasis added by Examiner)

It is noted that the declaration contains no clear nexus to the claimed invention that does not require that the sliding motion is provided after the healing takes place. For this reason, the declaration fails to be clearly relevant to the claimed invention.

The declaration under 37 CFR 1.132 filed November 27, 2001 by Ronald Smith is insufficient to overcome the rejection of claims 1-6, 8-10, and 24-31 based upon Cohen as set forth in the last Office action because:

There is no objective evidence or actual proof to support declarant's allegations and arguments.

Smith argues that Cohen is for a foot or weight bearing joint, but the present invention is directed to hand or non-weight bearing joints. However, upon reviewing the claims of record, it is clear that they are drawn to the treatment of a joint irrespective of location in the body and they do not preclude use in a foot.

The declarant next points out that he is familiar with the silicone implants mentioned in the Cohen background. The Examiner posits that silicone implants are not relevant to the Cohen invention, which uses an absorbable material. Furthermore, even if the silicone implants were considered relevant to the Cohen biodegradable implant, the declaration is insufficient in this regard because declarant states that the silicone implants "permit essentially no motion." This suggests that some motion is provided or at least this statement is vague in this regard. Additionally, declarant states that "some bending of the continuous fibrous tissue body, which can take place when

Art Unit: 3738

sufficient force is applied." Again, this suggests that some motion is provided and the only difference between Cohen's device and the present device is a matter of degree of motion. For this reason, this line of argument is considered unpersuasive.

Subsequently, Smith states that ORTHOSORB absorbable pins, if implanted in a joint, would immobilize it. Again, Cohen mentions absorbable pins in the background of the disclosure, and thus, it is not relevant to Cohen's device as disclosed.

Next, declarant argues that Cohen "does not provide mobility to the toe joint." In response, the Examiner posits that this statement is speculative because the Cohen device was never tested. Furthermore, declarant even states that some motion is provided by fibrous tissue; see the second full paragraph of page 3 of the declaration.

Declarant concludes that Cohen does not provide an articulating joint. The Examiner posits that some joint motion is admitted by declarant and the rest is a matter of relative degree. Since the claims do not specify the degree of motion provided, the argument is not considered relevant to the claimed invention.

Finally, since the Smith declaration provides some evidence that motion does occur when fibrous tissue grows between bone ends of a toe joint, this evidence becomes a teaching of obviousness rather than unobviousness. For this reason, the Examiner posits that claimed invention is considered at least clearly obvious over Cohen.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be

Art Unit: 3738

applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
Art Unit 3738